CATHETERIZATION ASSEMBLY

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 60/708,893, filed Aug. 17, 2005, the content of which is hereby incorporated by reference in its entirety into this disclosure.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to catheter assemblies. More particularly, the present invention relates to catheter assemblies having multiple functions.

[0004] 2. Background of the Invention

[0005] Short term, or repeated catheterization of an individual's urinary bladder is a common practice today for many persons who are in a hospital setting, a nursing home, doctor's office, rehabilitation facility or at home. For instance, a patient is sometimes catheterized to treat such conditions as urinary retention, the inability to evacuate urine, or for the purpose of obtaining a sterile urine specimen from a patient in a doctor's office.

[0006] The need for intermittent catheterization of an individual sometimes arises due to problems typically associated with long term use of indwelling catheters, such as infections, urethral damage, and bladder damage. Long term use of an indwelling catheter is also a risk factor for bladder cancer. This is often the case for persons having a neurogenic urinary condition, such as in a spinal cord injury, multiple sclerosis, stroke, trauma or other brain injury. Conditions that interfere with the individual's ability to voluntarily void the bladder may also arise post-surgically or as a result of benign prostatic hypertrophy or diabetes. Many of the affected individuals are capable of, and would prefer to perform self-catheterization. For many, the level of risk and discomfort of repeated catheterizations carried out over the course of a day (at 3-6 hour intervals, for example) are offset by the accompanying convenience, privacy or self-reliance that is achieved. Some of the major difficulties that arise in self-catheterization are the lack of satisfactory catheterization kits, the problem of maintaining the required level of sanitation during the procedure, and the difficulty of sometimes performing the procedure under conditions of restricted space and privacy.

[0007] In assisted, or non self-catheterizations, it is common practice in hospitals to employ a catheterization tray, which typically includes a sterile drape, gloves, a conventional catheter, antiseptic solution, swabs, lubricant, forceps, underpad and a urine collection container. Assisted catheterization is usually performed with the patient in a supine position. Maintaining a sterile field during the procedure can still be a problem, however, and the "cath tray" procedure is impractical for use with some individuals and situations today.

[0008] Many individuals with spinal cord injuries or other neurological diseases routinely perform intermittent catheterization several times a day using conventional catheters or kits and "clean technique." Clean technique means that the urethral area is initially swabbed with antiseptic, and efforts are made to avoid contamination of the catheter during the procedure. The user's hands are not sterile and a sterile field is not maintained. Clean technique is used instead of sterile technique, generally, for two reasons. First, it is very difficult, if not impossible, for individuals who are performing self-catheterization to adhere strictly to sterile technique. Secondly, these individuals are required to catheterize themselves between 3 and 6 times a day, and the cost of a new sterile catheter and the accessories required to perform sterile catheterization become excessively expensive for many users. Sometimes an individual will reuse a "cleaned" catheter. As a result, the use of non-sterile technique will many times result in contamination and subsequent infection of the urinary tract, causing significant morbidity and cost to the patient and society.

[0009] Even if cost considerations were not a major consideration for the user, with most conventional self-contained sterile units where the collection bag doubles as the catheter insertion cover, the catheter is extremely difficult for the user to grasp and insert. This is particularly a problem for self-catheterization users who may also have neurological problems that limit manual dexterity. Also, with some of the available catheter kits and methods, the catheter is either not sufficiently lubricated during insertion (and thus requires the additional application of possibly non-sterile lubricant), or the catheter is too slick with lubricant and cannot effectively be grasped through an insufficiently flexible bag. As a practical matter, most individuals who would prefer to self-catheterize cannot conveniently do so, and maintain the required level of sanitation using many of the existing catheterization apparatus.

[0010] A significant difficulty with conventional catheterization assemblies that merely package the catheter inside a sterile urine collection bag is that the flexible bag is typically neither thin-walled and pliant enough to permit grasping and feeding the catheter into the urethra, nor is it sufficiently rigid for accurate urine output measurement or for specimen removal. With some of the available catheter kits, there is also the further problem of a flexible or slippery catheter tending to drop down into the collection bag. In this circumstance, the user must first maneuver the catheter tip back to the bag opening before the catheter can be inserted into the patient's urethral opening.

[0011] Some catheterization devices in use today employ hydrophilic catheters that are self-lubricating when wetted with water prior to use. Furthermore, there are devices used for wetting a hydrophilic urinary catheter, which include a wetting receptacle that defines a wetting fluid receiving area for receiving the catheter and a wetting fluid container.

[0012] While the elimination of a dry catheter and lubricant may have some advantages, a serious drawback that is common to many hydrophilic catheter arrangements and catheterization methods is the tendency for the wetting liquid to flow out of the end of the catheter and onto the user or the user's bed or wheelchair as the catheter is drawn out of its packaging. Another drawback is that some hydrophilic catheter kits do not prevent the slippery hydrophilic catheter from falling down into an attached urine collection bag. As a consequence, the user must manipulate the catheter tip back to the bag opening before the catheter can be inserted into the patient's urethra. If the catheter slips into the urine collection bag after removal from the urethra, it can skew the urine collection volume. Still another problem with some conventional devices is that the wetting liquid can pool with the collected urine, skewing volume measurements and urinalysis results.